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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/069,228 04/27/98 PLOWMAN

G 234/118

EXAMINER

HM12/1010

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HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/069,228

Applicant(s)

PLOWMAN ET AL.

Examiner

Anne Holleran

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-5, 9 and 23-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 9, 23-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendment filed July 12, 2001 is acknowledged.

Claims 38-40 are cancelled.

Claims 2-5, 9, and 23-37 are pending and examined on the merits.

***Claim Rejections Withdrawn:***

2. The rejection of claims 36 and 38-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to claim 36 and the cancellation of claims 38-40.

3. The rejection of claims 38-40 under 35 U.S.C. 102(e) as being anticipated by either U.S. Patent 5,614,609, U.S. Patent 5,789,565 or U.S. Patent 5,811,245 is withdrawn in view of the cancellation of claims 38-40.

***Claim Rejections Maintained:***

4. The rejection of claims 9, 23-26, 28, 35 and 36 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record.

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Applicant's arguments have been carefully considered but are unpersuasive. Applicant asserts that because the specification sets forth the amino acid sequence of SEQ ID NO: 2 and sets forth specific fragments, that the fact that the fragments are claimed with open languages (use of "comprising") is irrelevant to the issue of written description of the claimed inventions, and that the specification need not provide literal support for each species encompassed by a claimed genus. Applicant asserts that the teaching of the amino acid sequence of SEQ ID NO: 2 is representative of the genus of nucleic acid products encompassed by the claims. This argument is not persuasive because the genus of claimed polynucleotide products is highly variant, and the structure of SEQ ID NO: 2 (which provided polynucleotides encoding SEQ ID NO: 2) does not appear to be representative of the full scope of the claimed polynucleotide products, which may encompass yet to be discovered polynucleotide products, such as splice variants and mutants, for example. Such species have not been described structurally by the specification.

5. The rejection of claims 2-5, 9 and 23-37 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility, or a well established utility, is maintained for the reasons of record.

Applicant's arguments have been carefully considered, but are unpersuasive. The characterizations, in the specification, of the ALK-7 protein (having amino acid sequence of SEQ ID NO: 2) pointed to by applicant do not confer a specific and substantial asserted utility upon the claimed polynucleotide products because the specification fails to establish that the expression (or lack thereof) is associated with diseases such as Parkinson's disease, Huntington's

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disease, or Alzheimer's disease. The specification fails to establish a biological function or association with a disease state. Absent this, the assertions by the specification are merely invitations to research to further characterize the claimed polynucleotide products.

6. The rejection of claims 2-5, 9, and 23-37 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran  
Patent Examiner  
October 7, 2001

AC

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